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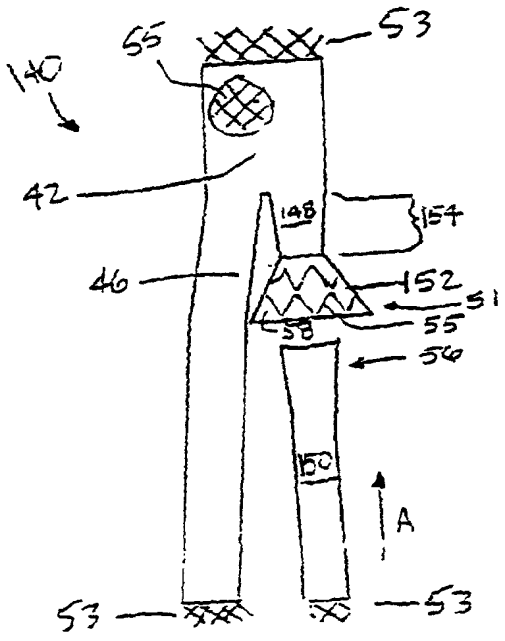
(54) Title: IMPROVED-GUIDEWIRE-ACCESS MODULAR INTRALUMINAL PROSTHESIS WITH CONNECTING SECTION



(57) Abstract: A multi-component intraluminal prosthesis is adapted for insertion into and in vivo assembly within a body lumen to repair the lumen, the components including secure and/or fluid-tight mating sections. The prosthesis comprises a female mating member comprising a main body portion, a funnel-shaped end, and a sealing segment connecting the main body portion to the funnel-shaped end; and a male mating member adapted for in vivo assembly with the sealing segment of the female mating member. The sealing segment may be essentially cylindrical or it may taper with decreasing diameter from the main body to the funnel-shaped end. The sealing segment and adjacent funnel-shaped end may together form an hourglass-shaped end. A biocompatible graft material may cover the inner surface of the funnel-shaped end. To secure a fluid-tight seal, the outer surface of the male member and the inner surface of the female member are covered with a biocompatible graft material in their respective mating segments. The prosthesis may form a bifurcated intraluminal prosthesis adapted, for example, for deployment in the infra-renal aorta and the iliac arteries, where the main body component forms the main aortic body, the integral first leg member forms the first iliac segment, and the second leg member forms the second iliac segment. An alternative prosthesis includes a primary member having a main body portion, a first dependant member attached radially thereto, and a female mating portion dependant from the main body portion, and a second dependant member having a male mating portion adapted to mate with the female mating portion.

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IMPROVED-GUIDEWIRE-ACCESS MODULAR INTRALUMINAL PROSTHESIS WITH CONNECTING SECTION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority based upon U.S. Patent Application Serial No. 09/327,069, filed on June 7, 1999.

TECHNICAL FIELD

The present invention relates generally to intraluminal grafts or "stents" and, more specifically, to improved-guidewire-access modular intraluminal prostheses having a sealing section where one module attaches to another.

BACKGROUND OF THE INVENTION

A stent is an elongated device used to support an intraluminal wall. In the case of a vascular stenosis, a stent provides an unobstructed conduit for blood in the area of the stenosis. Such a stent may also have a layer of prosthetic material that covers or lines the inside or outside thereof. Such a covered or lined stent is commonly referred to in the art as an intraluminal prosthesis, an endoluminal or endovascular graft (EVG), or a stent-graft. As used herein, however, the term "stent" is a shorthand reference referring to a covered or uncovered such stent.

Such a prosthesis may be used, for example, to treat a vascular aneurysm by removing the pressure on a weakened part of an artery so as to reduce the risk of rupture. Typically, an intraluminal stent or prosthesis is implanted in a blood vessel at the site of a stenosis or aneurysm endoluminally, i.e. by so-called "minimally invasive techniques" in which the stent, restrained in a radially compressed configuration by a sheath or catheter, is delivered by a stent deployment system or "introducer" to the site where it is required. The introducer may enter the body through the patient's skin, or by a "cut down" technique in which the entry blood vessel is exposed by minor surgical means. When the introducer has been threaded into the body lumen to the stent deployment location, the introducer is manipulated to cause the stent to be released from the surrounding sheath or catheter in which it is restrained (or alternatively the surrounding sheath or catheter is retracted from the stent), whereupon the stent expands to a predetermined diameter at the deployment location, and the introducer is withdrawn. Stent expansion may be effected by spring

elasticity, balloon expansion, or by the self-expansion of a thermally or stress-induced return of a memory material to a pre-conditioned expanded configuration.

Modular stents and prostheses are known in the art for *in vivo* assembly, particularly as applied to a bifurcated artery or vein, such as, for example, the bifurcation in the mammalian aortic artery into the common iliac arteries. The endoluminal navigation of a second component to find and mate with a previously deployed first component can be difficult.

Typically, the surgeon must navigate a guidewire to find an opening in the previously placed component, where the second component is to be mated therewith. Because of the tortuosity of the anatomy, the difficulty of visualizing that opening via fluoroscopy, and the two-dimensional nature of the fluoroscopic image, accessing that opening with the guidewire is one of the most difficult and time-consuming aspects of deploying such a prosthesis. Additionally, because of the difficulty in making the connection with that opening, the guidewire may inadvertently miss the opening and dislodge thrombus or pierce a wall of the lumen in which the prosthesis is being placed.

In a design known prior to the invention and as shown in Fig. 1, a body 30 disposed in the infrarenal area of the aorta with an integral elongated segment 32 extending into a first iliac artery 16 also comprises an integral funnel-shaped segment 34 alongside the elongated segment. Funnel-shaped segment 34 is adapted to capture guidewire 18 introduced from the iliac artery 16' into mouth 36 and to prevent the guidewire from contacting artery wall 26. The second modular component of the graft 37 is then inserted along guidewire 18 into funnel-shaped segment 34 from the iliac artery 16' and thus guided to a connection with first part body 30 at port 38. No particular type of connection between body 30 and second modular component 37 is disclosed in this prior known construction except as shown in Fig. 1.

SUMMARY OF THE INVENTION

The present invention provides an intraluminal prosthesis adapted for insertion into and assembly within a body lumen to repair the lumen. The prosthesis comprises a female mating member comprising a main body portion, a funnel-shaped end, a connecting segment connecting the main body portion to the funnel-shaped end; and a male mating member adapted for secure and/or fluid-tight assembly with the connecting segment

of the female mating member. The connecting segment may be essentially cylindrical or it may taper with decreasing diameter from the main body to the funnel-shaped end. The connecting segment and adjacent funnel-shaped end may together form an hourglass-shaped end.

A biocompatible material may cover one or both of the inner mating surface of the sealing segment and the outer mating surface of the male mating member adapted for contact with the sealing segment. The biocompatible graft material may cover the inner surface of the funnel-shaped end, and in particular, may cover the outer surface of the entire prosthesis except for the funnel-shaped end, which is covered only on the inner surface thereof.

The prosthesis may be bifurcated into first and second extensions depending from the main body section, wherein one or both of the extensions comprise an integral female mating member with a connecting segment as disclosed and claimed herein. One extension may comprise an integral first leg member that depends from the main body alongside the integral female mating member extension into which the male mating member mates to comprise a second leg member. Specifically, the prosthesis may form a bifurcated aortic intraluminal prosthesis adapted for deployment in the infra-renal aorta and the iliac arteries, where the main body component forms the main aortic body, the integral first leg member forms the first iliac segment, and the second leg member forms the second iliac segment.

The invention also comprises a bifurcated intraluminal prosthesis comprising a tubular primary member having a main body portion, a tubular first dependant member attached radially thereto, and a female mating portion dependant from the main body portion and having an opening. A tubular second dependant member comprising an elongated body and a male mating portion is adapted for insertion through the opening and in vivo assembly securely with the female mating portion. The female mating portion may taper from a first larger diameter to a second smaller diameter at the opening and the male mating portion may be flared from a third diameter slightly smaller than the second diameter to a fourth diameter slightly smaller than the first diameter.

It is to be understood that both the foregoing general description and the following detailed description are exemplary, but are not restrictive, of the invention.

BRIEF DESCRIPTION OF DRAWING

The invention is best understood from the following detailed description when read in connection with the accompanying drawing. It is emphasized that, according to common practice, the various features of the drawing are not to scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawing are the following figures:

Fig. 1 is a schematic illustration of a cross-section of a bifurcated artery, showing an intraluminal prosthesis of the prior art inserted therein.

Fig. 2 is a schematic illustration of an exemplary intraluminal prosthesis of the present invention having a funnel-shaped female mating member and a generally cylindrical sealing section.

Fig. 3 is a schematic illustration of another exemplary intraluminal prosthesis of the present invention having a funnel-shaped female mating member and a tapered sealing section.

Figs. 4A and 4B are schematic illustrations of an exemplary intraluminal graft structure of the present invention having a female mating member with an hourglass-shaped end and a male mating member having a mating hourglass-shaped end, shown in disassembled and assembled configurations, respectively.

Fig. 5 is a schematic illustration of another exemplary intraluminal prosthesis of the present invention having an off-center bifurcation.

DETAILED DESCRIPTION OF INVENTION

Referring now to the drawing, wherein like reference numerals refer to like elements throughout, Figs. 2 – 4B are schematic illustrations of exemplary intraluminal prostheses of the present invention.

Prosthesis 40, as shown in Fig. 2, comprises a main body component 42 from which an integral first leg portion 46 and an integral female mating member 48 depend therefrom. As used herein, "distal" refers to the end farthest from the access location outside the body lumen, and "proximal" refers to the end closest to the access location outside the body lumen. Integral first leg portion 46 is adapted to extend into one branch of a bifurcated artery (such as branch 16 as shown in Fig. 1, when prosthesis 40 is mounted into a similar

artery). Female mating member 48 is adapted to be positioned aligned with the other artery branch (16'). Prosthesis 40 also comprises an independent, tubular second leg portion 50 adapted for mating with female mating member 48 by insertion along the direction of arrow "A".

Female mating member 48 has a proximal end 51 comprising a funnel-shaped passage 52 adapted to help direct the guidewire into the female mating member, thereby facilitating improved guidewire access during placement of the prosthesis. Funnel-shaped passage 52 may comprise stent structure 55 mounted outside of graft material 58. Stent structure 55 may be mounted outside of graft material 58 in funnel-shaped passage 52 as shown in Fig. 2 so that the guidewire will not become entangled between the stent wires and the graft material. In another embodiment, not shown, graft material 58 may cover both the inside and outside of stent structure 55 in funnel-shaped passage 52. As shown in Fig. 2, the remainder of prosthesis 40 comprises graft material 58 on the outside of stent structure 55 (shown in circular cutaway) except for at anchoring ends 53. Anchoring ends 53 comprise sections of stent having no overlying graft material (and, preferably, no underlying graft material either), so that body tissue may grow around the stent structure of ends 53 to more permanently anchor the stent in place.

In accordance with the present invention, prosthesis 40 also comprises connecting section 54 between funnel-shaped passage 52 and main body 42. Connecting section 54 is adapted for securing second leg portion 50 into female mating member 48. As shown in Fig. 2, connecting section 54 is essentially cylindrical with the same diameter throughout. In an alternative embodiment, shown in Fig. 3, female mating member 148 of prosthesis 140 may have a connecting section 154 that has a tapered diameter decreasing between main body 42 and funnel-shaped passage 152. Second leg portion 150 may have a mating tapered section 56 adapted to mate snugly with connecting section 154. To provide a fluid-tight seal between second leg portion 50, 150 and respective connecting section 54, 154, connecting section 54, 154 may be lined inside with graft material (not shown) whereas second leg portion 50, 150 may be covered outside with graft material. In this way, the interface between second leg portion 50, 150 and respective connecting section 54, 154 provides graft-material-to-graft-material contact to effect a tight seal.

In yet another alternative embodiment, as shown in Figs. 4A and 4B, exemplary prosthesis 60 may have a female mating member 248 with a tapered connecting section 254 and adjacent funnel-shaped passage 252 that together form an hourglass-shaped end 256. Second leg portion 250 thus includes a mating hourglass-shaped end 256'. Mating hourglass-shaped ends 256 and 256' allow second leg portion 250 to be inserted into main body 42 along arrow "A" in a compressed form, expanded, and then tensionally pulled opposite arrow "A" until it locks into place as shown in Fig. 4B. The self-locking hourglass seal decreases the likelihood of placing the interlocking modular component too far into the graft, which can result in clinical problems such as inadequate sealing to the iliac, thrombosis, or stenosis in some cases.

In prosthesis 60 as shown in Figs. 4A and 4B, similar to the other embodiments shown and described above, funnel-shaped passage 252 may comprise stent structure covered by graft material on the inside to prevent entanglement of the guidewire during navigation therein. Additionally, as shown in Figs. 4A and 4B, funnel-shaped passage 252 may also be covered outside with graft material 58. The remainder of prosthesis 60 typically comprises stent structure 55 (shown in circular cutaway) covered outside by graft material 58. Where anchoring ends (not shown in Figs. 4A and 4B) are present, the stent structure is typically left uncovered by graft material. To effect a fluid-tight seal, the stent structure in both funnel-shaped passage 252 and connecting section 254 may be covered on the inside by graft material (not shown) wherein second leg portion 250 comprises graft material 58 on the outside of stent structure 55 (shown in circular cutaway) so that graft-material-to-graft-material contact is provided at the interface of hourglass-shaped end 256 with funnel-shaped passage 252 and connecting section 254.

Any of the embodiments shown herein may include radiopaque markers positioned on the stent as necessary to provide "vision" via fluoroscopy to the attending surgical team. "Radiopaque marker" as used herein encompasses any discrete area of different radiopacity as compared to a surrounding area. Specifically, such markers may be advantageously placed at the mating ends of the female and male mating members to facilitate mating. In particular, with respect to the hourglass-shaped ends 256 and 256' shown in Figs. 4A and 4B, radiopaque markers may be placed at the narrow diameter waists 257 and 257' of female mating member 248 and second leg portion 250, respectively, to facilitate proper alignment.

A prosthesis of the present invention may be constructed with any materials known in the art, and may be deployed using an introducer catheter such as those well-known in the art. The stent material used to form a prosthesis of the present invention is preferably self-expanding, shape-memory nitinol, but may be elastically or thermally self-expanding, balloon expandable, or expandable by any method known in the art. The graft material may be any material known and used for such purposes in the art, including fluid-impermeable textiles or polymers such as polyester, polyurethane, or polytetrafluoroethylene. Although illustrated herein with respect to a bifurcated design, the funnel-shaped end and adjacent sealing section may be applied to non-bifurcated and multi-branched modular intraluminal prosthesis designs as well.

Yet another embodiment of the present invention is shown in Fig. 5. Fig. 5 shows bifurcated intraluminal prosthesis 500 comprising a primary member 501 comprising a tubular main body portion 502 having a first dependant member 504 attached radially thereto, and a female mating portion 506 coaxially dependent therefrom and having an opening 508. This radial attachment contemplates that first dependant member 504 is attached to the side of, rather than an end of, tubular main body portion 502 and, preferably, extends downwardly at an acute angle relative to the longitudinal axis of main body portion 502. A second dependant member 510 comprising an elongated body 512 and a male mating portion 514 is adapted for in vivo assembly securely with female mating portion 506. As shown in Fig. 5, female mating portion 506 tapers from a first larger diameter d_1 where it connects to main body portion 502 to a second smaller diameter d_2 at opening 508. Male mating portion 514 is flared from a third diameter d_3 to a fourth diameter d_4. To assure a snug fit between male mating portion 514 and female mating portion 506, diameter d_3, in an unconfined state, is slightly larger than diameter d_2 and diameter d_4, in an unconfined state, is slightly larger than diameter d_1. Of course, confined diameter d_3 is necessarily slightly smaller than diameter d_2, and confined diameter d_4 is necessarily slightly smaller than diameter d_1, such that mating portion 514 exerts a radially outward force on main body portion 502 once assembled. Although shown tapered such that opening 508 has a smaller diameter than diameter d_1 of main tubular section 502, female mating member 506 may have the same diameter throughout or may taper outwardly to an opening having a diameter larger than diameter d_1 of the main tubular portion.

The off-center bifurcation of primary member 501 such that the first dependent member 504 attaches radially to main tubular portion 502, rather than dividing the main tubular portion into two approximately equal diameter leg portions, provides female mating portion 506 with a relatively large diameter. This large diameter allows for easy insertion of the guidewire for delivery of the second dependent member 510. The tapered configuration of female mating portion 506 and male mating portion 514 is beneficial so that fluid flow along arrow *B* helps drive the connecting portions even more firmly together. Male mating portion 514, which comprises a first tapered region as shown in Fig. 5, connects to elongated body 512 via a second tapered regions 513. Portion 514 tapers from d_4 to d_3 with a first degree of taper and region 513 tapers from d_3 to d_5 with a second degree of taper more extreme than the first degree. Other configurations may be provided, however, such as configurations having a single degree of taper in both portion 514 and region 513, more than two distinct tapered regions, an additional constant diameter section between the two tapered regions, an hourglass configuration as shown in Figs. 3 and 4, or any combination of tapered and straight sections as may be needed to snugly connect to female mating portion 506. Furthermore, although shown in Fig. 5 such that female mating portion 506 is coaxial with main body portion 502 of primary member 501 such that the female mating portion is essentially a "concentric" reducer, female mating portion 506 may also be an "eccentric" reducer where the central axis through diameter d_2 is not coaxial with the central axis through diameter d_1. The male mating portion may having an accordingly eccentric taper to mate with such a female mating portion.

Although illustrated and described herein with reference to certain specific embodiments, the present invention is nevertheless not intended to be limited to the details shown. Rather, various modifications may be made in the details within the scope and range of equivalents of the claims and without departing from the spirit of the invention.

What is Claimed:

1. A intraluminal prosthesis adapted for insertion into and assembly within a body lumen to repair the lumen, said prosthesis comprising:

a tubular female mating member comprising a main body portion, a funnel-shaped end, and a connecting segment connecting said main body portion to said funnel-shaped end; and

a tubular male mating member adapted for in vivo assembly securely with the connecting segment of the female mating member.

2. The prosthesis of claim 1 wherein the connecting segment is essentially cylindrical.

3. The prosthesis of claim 1 wherein the connecting segment tapers with decreasing diameter from said main body to said funnel-shaped end.

4. The prosthesis of claim 3 wherein the connecting segment and adjacent funnel-shaped end together form an hourglass-shaped end.

5. The prosthesis of claim 1 wherein said prosthesis is in the form of a first compressed configuration, prior to deployment, for introducing said prosthesis into the body lumen, and a second expanded configuration after deployment of said prosthesis within the body lumen.

6. The prosthesis of claim 5 wherein the prosthesis is adapted to be converted from the compressed configuration to the expanded configuration by a mechanism selected from the group consisting of: balloon expansion, shape memory material self-expansion, and elastic self-expansion.

7. The prosthesis of claim 1 further comprising a biocompatible graft material covering one or both of an inner mating surface of the connecting segment and an outer mating surface of the male mating member adapted for contact with said connecting segment.

8. The prosthesis of claim 1 wherein a biocompatible graft material covers an inner surface of the funnel-shaped end.

9. The prosthesis of claim 8 wherein said biocompatible graft material also covers an inner surface of the connecting segment.

10. The prosthesis of claim 9 wherein said biocompatible graft material also covers at least a portion of the outside of said female mating member.

11. The prosthesis of claim 9 wherein an outer surface of at least a mating section of said male member is covered with said biocompatible graft material.

12. The prosthesis of claim 1 wherein a biocompatible graft material covers (a) an outer surface of all of said prosthesis except for one or more anchoring ends adapted to allow tissue growth thereabout once deployed within said body lumen and, optionally, said funnel-shaped end, and (b) an inner surface of said funnel-shaped end.

13. The prosthesis of claim 1 wherein the prosthesis is branched into at least two extensions depending from said main body section, wherein at least one of said extensions comprises an integral female mating member and said connecting segment.

14. The prosthesis of claim 13 wherein at least one of said extensions comprises an integral first leg member that depends from said bifurcation alongside said integral female mating member.

15. The prosthesis of claim 14 wherein the male mating member comprises a second leg member.

16. The prosthesis of claim 15 wherein said prosthesis forms a bifurcated aortic intraluminal prosthesis adapted for deployment in the infra-renal aorta and the iliac arteries, said main body component adapted to form a main aortic body, said integral first leg member forming a first iliac segment, and said second leg member forming a second iliac segment.

17. The prosthesis of claim 16 wherein the connecting segment and the adjacent funnel-shaped end of the female mating member together form an hourglass-shaped end, and in which the second leg member comprises a mating hourglass-shaped end adapted to interlock with said female mating member hourglass-shaped end.

18. A bifurcated intraluminal prosthesis adapted for insertion into and assembly within a bifurcated body lumen to repair the lumen, said prosthesis comprising:

a tubular female mating member comprising a main body portion, an integral first leg member depending from the main body portion, an extension depending from the main body portion alongside the first leg member, the extension comprising a funnel-shaped end and a connecting segment between said main body portion and said funnel-shaped end, said female mating member having an outer surface covered with a biocompatible graft material except for one or more anchoring ends and, optionally, said funnel-shaped end, and said funnel-shaped end having an inner mating surface covered with said biocompatible graft material; and

a male mating member adapted for in vivo assembly securely with the connecting segment of the female mating member and having an outer surface covered with said biocompatible graft material.

19. A bifurcated intraluminal prosthesis adapted for insertion into and assembly within a body lumen to repair the lumen, said prosthesis comprising:

a tubular primary member having a main body portion, a tubular first dependant member attached radially thereto, and a female mating portion dependant from the tubular main body portion and having an opening; and

a tubular second dependant member comprising an elongated body and a male mating portion adapted for insertion through the opening and in vivo assembly securely with the female mating portion.

20. The intraluminal prosthesis of claim 19 wherein the female mating portion is coaxial with the main body portion.

21. The intraluminal prosthesis of claim 19 wherein the female mating portion tapers from a first larger diameter to a second smaller diameter at the opening; and the male mating portion is flared from a third diameter slightly smaller than the second diameter to a fourth diameter slightly smaller than the first diameter.

22. The intraluminal prosthesis of claim 19 wherein the male mating portion comprises a first tapered region having a first degree of taper and the second dependent member further comprises a second tapered region having a second degree of taper more extreme than the first degree of taper.

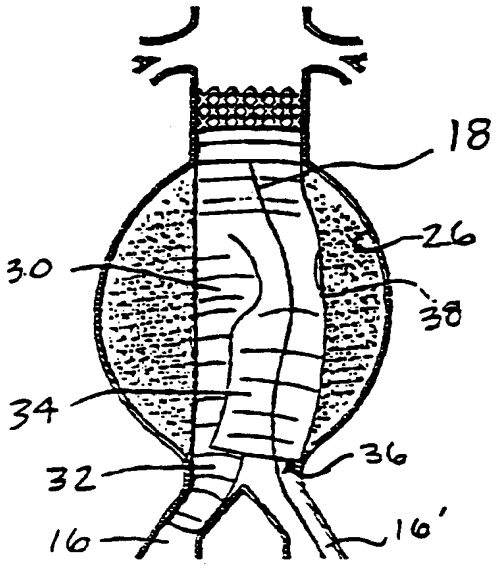

FIG 1
(PRIOR ART)

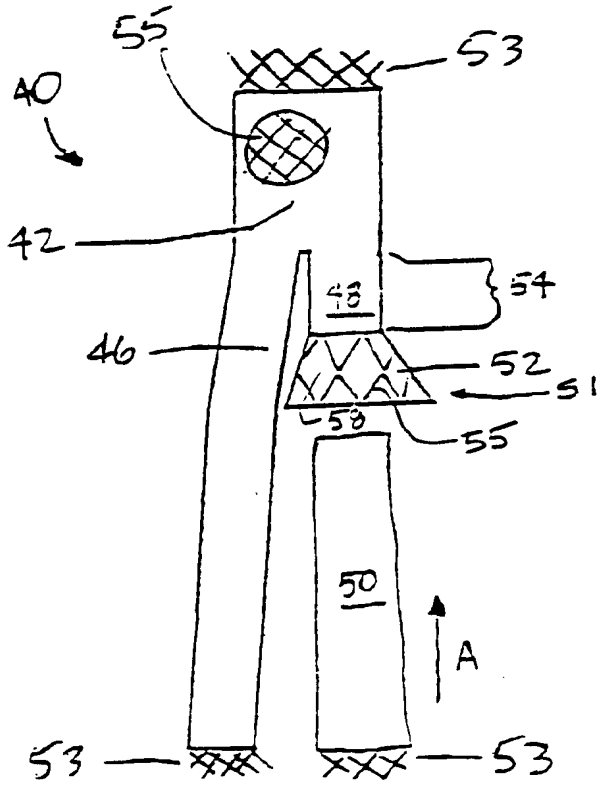

FIG. 2

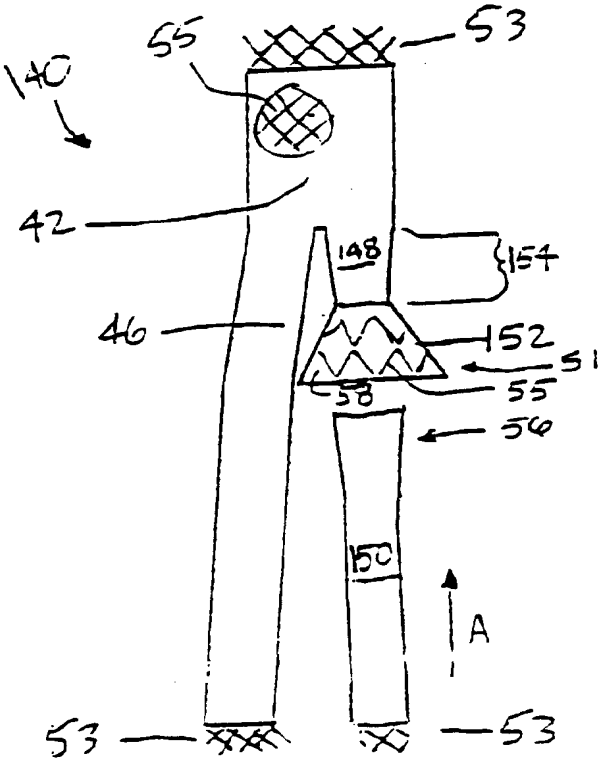

FIG. 3

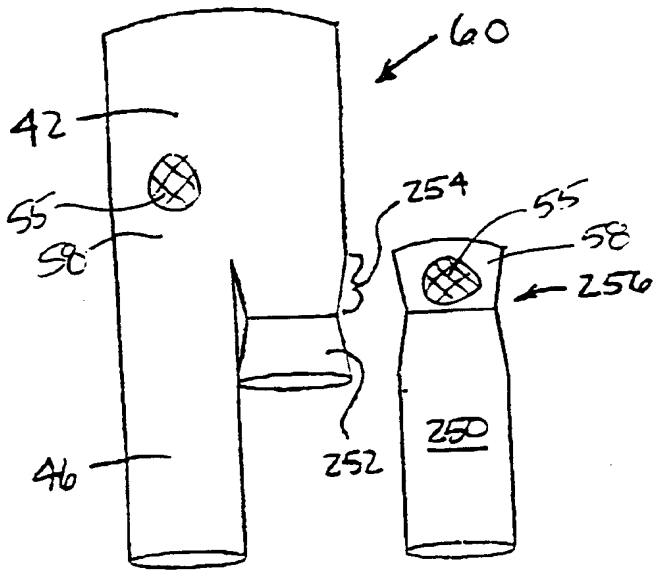

FIG. 4A

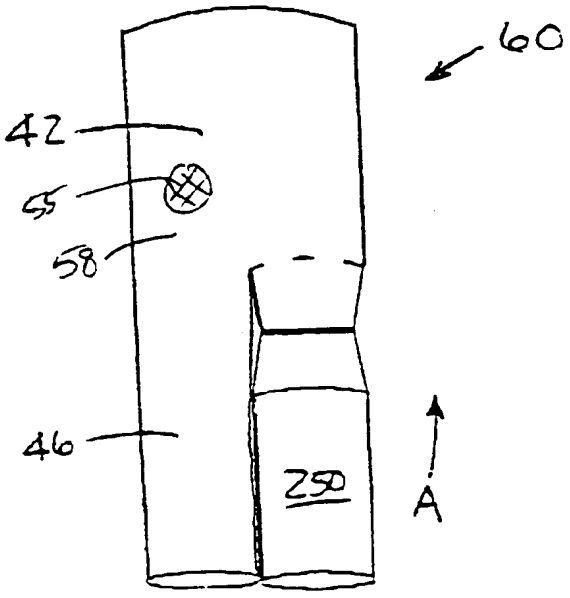

FIG. 4B

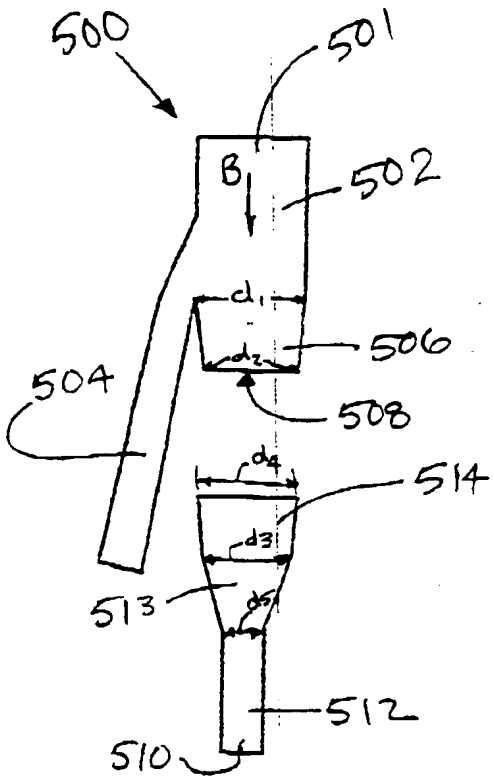

FIG. 5

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 00/40132

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 6 030 415 A (CHUTER TIMOTHY A M) 29 February 2000 (2000-02-29) figures 1-5,7-9	1,2,5,6, 12,13, 19,20
A	claim 1	3,4, 7-11, 14-18, 21,22

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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Date of the actual completion of the international search	Date of mailing of the international search report
6 November 2000	13/11/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 00/40132

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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A		3,4, 7-11, 15-18, 21,22

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